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No. 03-388

IN THE

Supreme Court of the United States

DENNIS BATES, ET AL.,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

On Writ Of Certiorari to the United States Courts of Appeals for the Fifth Circuit

AMICUS CURIAE BRIEF OF THE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF PETITIONERS

TODD A. SMITH
1050 31st St., N.W.
Washington, DC 20007
(202) 965-3500
President,
The Association of Trial Lawyers of America

R.C. WESTMORELAND *
WESTMORELAND, VESPER, SCHWARTZ & QUATTRONE
8025 Black Horse Pike
Suite 500
West Atlantic City, NJ 08232
(609) 645-1111
Attorney for Amicus Curiae
**Counsel of Record*

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No. 03-88

IN THE

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DENNIS BATES, ET AL.,

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v.

DOW AGROSCIENCES LLC,

Respondent.

AMICUS CURIAE BRIEF OF THE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF PETITIONERS

IDENTITY AND INTEREST OF *AMICUS CURIAE*

The Association of Trial Lawyers of America ["ATLA"] respectfully submits this brief as amicus curiae. The parties have filed letters of consent to the filing of amicus briefs with this Court.[1]

ATLA is a voluntary national bar association whose approximately 50,000 trial lawyer members primarily represent individual plaintiffs in civil actions brought under state tort law.

Frequently our members have represented farmers whose crops have been damaged or destroyed by pesticides that were either untested,

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[1] Pursuant to Rule 37.6, Amicus discloses that no counsel for a party authored any part of this brief, nor did any person or entity other than Amicus Curiae, its members, or its counsel make a monetary contribution to the preparation or submission of this brief.

badly formulated, defectively produced, or falsely marketed.

Because pesticide labels are regulated by FIFRA, there are, to our knowledge, only two reported cases (both state supreme court decisions) over the past 20 years where farmers' state crop damage claims have survived FIFRA's preemption clause. As a result, farmers claiming crop damages from harmful pesticides have been left without any remedy for the wrong done to them.

In ATLA's view, the legislative history of the Act since 1978 reveals that Congress did not intend FIFRA to preempt state common law tort actions for crop damage.

How do you explain to an American farmer that he has no remedy at law when his crops have been damaged or destroyed by an unsafe pesticide that the manufacturer claimed was safe? There is no reasonably acceptable explanation.

SUMMARY OF ARGUMENT

1. This case is an opportunity for the Court to correct two decades of injustice borne by farmers across America. Congress enacted the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to address safety and environmental concerns posed by such products. The Act precluded states from imposing requirements "in addition to or different from" the federal requirements under the Act. In 1978, Congress amended FIFRA to end EPA review of the efficacy of registered products. That amendment and its impact on the scope of FIFRA's preemptive scope, have been largely ignored by federal courts that have held farmers' state law claims for crop damage to be

preempted. Closer examination supports Petitioners' argument in this case that such claims are not preempted by FIFRA.

Congress enacted the Federal Pesticide Act of 1978 amending FIFRA, 7 U.S.C.A. § 136a (c)(5), authorizing the EPA to waive the requirement that producers submit data showing the efficacy of their products. Congress intended both to ease the regulatory burden on the industry and to leave the efficacy of agricultural pesticides to the judgment of the marketplace. The EPA subsequently adopted such a waiver by regulation, taking the federal government out of the business of regulating the efficacy of pesticides, focusing instead on protection of people and the environment.

These actions by Congress and the EPA removed property damage claims from the scope of FIFRA preemption. They draw a clear distinction between state claims for personal injury or environmental damage and those for property damage. The former are label-based because the label process requires review and approval of data relating to hazards to humans and the environment. Property damage claims are no longer label-based because the EPA in the label approval process no longer reviews the effect of a pesticide on crops. Petitioners' crop damage claims in this case are precisely the type of claim that Congress left to state regulation and the marketplace, including state tort law. This crucial distinction, however, has gone largely unnoticed by federal courts presented with such claims.

2. This Court has held that the general tort duties not to make false statements or misrepresentations in marketing materials are not requirements in

addition to or different from specific federal requirements for purposes of express preemption. FIFRA's preemption of state "requirements for labeling or packaging" does not encompass the general tort duties against false statement and misrepresentation. Nor are such tort duties displaced where they are the same as or parallel to federal requirements, so long as they do not conflict with those federal requirements.

In addition, as Congress made plain in the text of the preemption provision, FIFRA preempts only those state requirements that are "in addition to or different from those required under the Act." Because EPA has waived efficacy as a labeling requirement, there is no relevant federal requirement that would displace state law. Nor does it appear that Congress intended the EPA to regulate statements in producers' marketing materials, as distinguished from label contents.

To hold otherwise would grant producers complete immunity for wrongful crop damage. To the extent that Congress intended to benefit producers by amending FIFRA, Congress did so by easing the burden of regulation. Congress did not intend to deprive users of all legal redress.

3. The court below unaccountably ignored this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). FIFRA's express preemption provision is very similar to the provision in that case. Additionally, the *Medtronic* Court refused to give preemptive effect to FDA approval of a product that had been exempted from the agency's usual rigorous testing and review. This Court should hold in this case, as in *Medtronic*, that Petitioners' claims fall outside the scope of preemption created by Congress.

ARGUMENT

I. THE FIFRA EXPRESS PREEMPTION CLAUSE DOES NOT APPLY TO CROP DAMAGE CLAIMS.

A. Congress Amended FIFRA In 1978 To End EPA Regulation of Product Efficacy, Removing Crop Damage Claims From The Scope of FIFRA Preemption.

Congress enacted the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.* to address safety and environmental concerns posed by such products. *Wisconsin Public Intervenor v. Mortier,* 501 U.S. 597, 601 (1999). The Act preserved limited authority of the states to regulate such products, but precluded state requirements "in addition to or different from" the federal requirements.[2]

On July 6, 1977, the United States Senate reported its intent to amend FIFRA to allow the EPA to waive the requirement that producers submit data on the effect of agricultural pesticides upon crops,

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[2] 7 U.S.C § 136v provides:

(a) In General

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

The report recognized that the EPA's primary function was to protect humans and the environment and that all of EPA's resources should be directed to that end. It also noted that existing efficacy data was of questionable value and that manufacturers were unlikely to register non-efficacious products. In addition, it would reduce the regulatory burden upon manufacturers and leave efficacy of agricultural pesticides to those better able to judge such as producers, USDA, and the marketplace of users. S. Rep. No. 95-334, at. 2, 9, 19, 20, 28, and 73 (1977).

On September 30, 1978, Congress passed the Federal Pesticide Act of 1978 amending FIFRA. 7 U.S.C.A. 136a (c)(5) and authorizing the EPA to waive the efficacy requirement. Eight months later, on May 11, 1979, the EPA acted on that authority, restating the Congressional intent and proposing a regulatory waiver:

> The agency's viewpoint concerning waiver of efficacy data requirements is in line with the general belief among persons in the pesticide industry, the U. S. Department of Agriculture and the agricultural community that the efficacy of agricultural pesticides can be effectively regulated by the marketplace (in conjunction with extension services and university research personnel).
>
> The decision to pursue efficacy waiver as an agency policy stems from a need to reduce the amount of resources devoted to reviewing product performance so that additional effort could be devoted to the evaluation of health and safety data, and from a desire to reduce regulatory burdens in the pesticide registration process...therefore, commitment of the resources needed to fully evaluate this data for purposes of registration was determined to be less than the ideal use of limited resources for pesticide regulation.

44 Fed. Reg. 27932, 27938 (May 11, 1979).

On November 3, 1980, the EPA returned to the waiver question by issuing guidelines for pesticide assessment. 45 Fed. Reg. 72948 (Nov. 3, 1980). This rule more expansively stated that efficacy requirements for all pesticides are waived unless there is a direct impact on public health and that the industry as well as the United States government believes that the marketplace effectively regulates the efficacy of pesticides. 45 Fed. Reg. 72951. It also waived submission of phytotoxicity data where efficacy data is no longer required and clearly stated that consumer fraud claims would be left to state regulation, which the agency would simply monitor:

> The pesticide industry was generally supportive of the concept of efficacy waiver. . . . EPA . . . will monitor the impacts of the efficacy waiver policy to determine if . . . *consumer fraud* is effectively reported and curtailed through existing market institutions including state regulation processes and the USDA and the extension service, farmers associations and the marketplace.
>
> The agency expects that all registrants will perform the tasks necessary to assure themselves that the products the (sic) market will perform their intended functions when applied in accordance with label directions and commonly accepted pest control practices. The agency must rely upon the integrity of the industry, the soundness of extension service recommendations and the good judgment of

> pesticide users to insure that abuses seldom occur.

45 Fed. Reg. 72948, 72951 (Nov. 3, 1980) (emphasis added).

In EPA's view, Congress did not intend the waiver to confer immunity from state tort liability on producers. To the contrary, the EPA clearly anticipated that state tort suits would provide the incentive for producers to ensure the efficacy of their products. As the EPA stated in its proposed rule to waive the requirement for submission of efficacy data,

> The Agency expects and believes that registrants will ensure that their products are efficacious when used in accordance with label directions and commonly accepted practice because FIFRA at section 3(c)(5)(A) requires it and *because pesticide producers are aware that they are potentially subject to damage suits* by the user community if their products prove ineffective in actual use.

47 Fed. Reg. 40659, 40661 (Sept. 15, 1982) (emphasis added).

Indeed, in proposing that Code of Federal Regulations, Title 40, be amended to add a new section 158 incorporating its waiver of performance data review, the EPA specifically stated:

> This change is based on the Agency's perception that registrants routinely conduct extensive testing to assess the phytotoxicity of their products on their own, either to assess efficacy (in the case of herbicides), and/or to develop appropriate use instructions and precautionary labeling in order *to ensure that their products do not impart any detrimental effects (particularly*

> *on crops, ornamentals and other desirable plants) for which they could be liable.*

Pesticides Registration; Proposed Data Requirements, 47 Fed. Reg. 53192, 53196. (Nov. 24, 1982) (emphasis added).

The regulation was adopted and states, in pertinent part:

> The agency has waived all requirements to submit efficacy data unless the pesticide product...poses a threat to human health. . . However, each registrant must insure through testing that his products are efficacious when used in label directions and commonly accepted pest control practices.

40 C.F.R. § 158.640(b)(1).

Prior to the waiver, FIFRA required submission by a registered producer to the EPA of all testing data for a product's effects when used as intended and expressly preempted state claims once the EPA completed the label approval process. Claims were characterized as label-based, and therefore expressly preempted, when they related to the data that had been reviewed and approved by the EPA in a label approval process.

The effect of these congressional and EPA actions was to carve a small niche out of FIFRA's preemptive scope. Claims for crop damage caused by a registered product were no longer label-based because no testing data on the effect of the product on crops was submitted to or reviewed by the EPA in the FIFRA label approval process. Such claims could not, therefore, result in label requirements "in addition to or different" from those required by the Act. The benefits to the industry in not having to

submit efficacy data to the EPA was a trade-off for loss of preemption in crop damage cases.

Congress and the EPA have effectively drawn a clear distinction, for preemption purposes, between state claims made for personal injury or environmental damage and those made for property damage. The former are prima facie label-based because the label process requires review and approval of data relating to health of humans and the environment. Property damage claims are no longer label-based following the end of EPA review of the product's effects on crops. Stated differently, if efficacy is not a requirement of the EPA in its approval process, and a state tort claim is predicated only on the efficacy of the product, then the state claim is not "a requirement for labeling. . . in addition to or different from those required under this subchapter." 7 U.S.C.A. § 136v(b). State tort claims based upon damage caused by a pesticide's efficacy simply do not intrude upon or conflict with the existing federal requirements.

Petitioners' claims for defective design and negligent manufacture arise directly from the effect of Dow's herbicide, Strongarm, on crops when used as intended, and do not involve personal injuries or environmental damage. They are precisely the type of claims that Congress left to state regulation and the marketplace, including state common law tort duties.

B. Federal Courts Have Ignored the 1978 Amendment In Holding Crop Damage Claims Preempted By FIFRA.

Unfortunately, impact of Congress's action went largely unnoticed for 20 years by courts addressing preemption questions. During that time,

no less than seven U.S. Circuit Courts had well-established precedents holding crop damage claims preempted. None of those courts was apparently aware of the 1978 amendment, which was never raised or discussed in their decisions.

The EPA raised its voice in an *amicus curiae* brief filed in the California Supreme Court, explaining the reality of its process under FIFRA and that preemption of crop damage claims was not consistent with that reality. *See* U.S. Amicus Br., *Etcheverry v. TRI-AG Serv. Inc.*, No. S072524 (Cal. filed Mar. 1999). The court nevertheless held plaintiff's claims preempted, making a classic distinction without a difference by distinguishing phytotoxicity from crop damage. *Etcheverry v. Tri-Ag Service, Inc.*, 93 Cal. Rptr. 2d 36, 993 P.2d. 366 (2000). Phytotoxicity is defined in Webster's Dictionary as "poisonous to plants" and is specifically characterized by the EPA in its regulations as part of the efficacy domain. 45 Fed. Reg. 72948, 72950-51 (Nov 3, 1980).

In 2002, the Texas Supreme Court, in *American Cyanamid Co. v. Geye*, 79 S.W. 3d. 21 (Tex. 2002), properly interpreted Congressional intent and the EPA regulations, and held that the claims of peanut farmers whose crops were damaged by defendant's herbicide were not preempted under FIFRA.

The Fifth Circuit Court in this case affirmed a declaratory judgment grant of preemption by the trial court by distinguishing between express preemption and an "ordinary conflict preemption" case, stating that *American Cyanamid* was the latter, while this case is the former. *Dow Agrosciences LLC v. Bates,* 332 F.3d 323, 330 & n.13

(5th Cir. 2003). This characterization is clearly erroneous. As the Texas court itself stated: "This is an express preemption case," quoting FIFRA's express preemption provision, 7 U.S.C. § 136v(b), as the basis for its decision. *American Cyanamid*, 79 S.W. 3d. at 24.

Thus, the intent of Congress was an intentional transference of claims for a pesticide's efficacy from the EPA to a far superior arbiter of such claims – the marketplace. It took the federal government out of the business of warranting a product's efficacy when used and returned to its original purpose of protecting people and the environment. These new contours of the Act were supposed to return harmony between its original intent and the subsequently expected results. They did not. The federal circuits remained largely unaware of this development and its removal of crop damage claims from the scope of FIFRA's preemption. This case presents this Court with the opportunity to correct this glaring failure of justice.

II. FIFRA'S EXPRESS PREEMPTION CLAUSE DOES NOT PREEMPT STATE CONSUMER FRAUD AND DECEPTIVE TRADE PRACTICES ACTIONS.

A. State Actions For False Representations Are The Only Enforcement Tool Of The FIFRA Requirement Prohibiting False Statements Of A Product's Effectiveness And The Sole Remedy Available To Those Injured By The Falsity.

Petitioners' state law causes of action include not only claims of defective design and negligent

manufacture, but also claims based on false statements and misrepresentation. These claims too, ATLA submits, are not preempted under FIFRA.

7 U.S.C. § 136v(b) prohibits states from imposing requirements for labeling that are "in addition to or different from" those required under the Act. One question, then, is whether claims alleging crop damage due to false or misleading statements in producers' marketing materials are preempted as imposing requirements in addition to or different from the federal requirements.

This Court answered that question in its decisions in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

In *Cipollone*, this Court dealt with the Federal Cigarette Labeling & Advertising Act, which, unlike FIFRA, was narrowly directed solely towards the advertising of cigarettes. The plurality opinion by Justice Stevens stated, "The predicate of this claim is a state-law duty not to make false statements of material fact or to conceal such facts." 505 U.S. at 528.

Is that state-law duty the sort that imposes a requirement that results in preemption? The Court's response was that "Congress offered no sign that it wished to insulate cigarette manufacturers from longstanding rules governing fraud." *Id.* at 529. Rather, "State-law prohibitions on false statements of material fact do not create diverse, non-uniform and confusing standards." *Id.* The Court explained that, "[u]nlike state-law obligations concerning the warning necessary to render a product 'reasonably

safe,' state-law proscriptions on intentional fraud rely only on a single uniform standard: falsity." *Id.*

"Accordingly," the Court concluded, "petitioner's claim based on allegedly fraudulent statements made in respondents' advertisements is not preempted." *Id.*[3]

The opinion of Justice Blackman, concurring and dissenting in part, joined in by Justice Kennedy and Justice Souter, characterized the plurality holding as follows: "The plurality states that fraudulent misrepresentation claims (at least those involving false statements of material fact in advertisements) are 'predicated not on a duty based on smoking and health' but rather on a more general obligation – the duty not to deceive,' and therefore are not pre-empted." *Id.* at. 543.

In *Medtronic*, after a thorough review of the legislative history of the Medical Device Amendments of 1976, this Court found nothing to indicate that Congress "intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective products." 518 U.S. at 491.

The Court made clear the express preemption provision there did not deny a state "the right to provide a traditional damages remedy for violations of common-law duties when those duties *parallel* federal requirements." *Id.* at 495. Nor did it preempt "state or local requirements that are *equal to, or*

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3 The Supreme Court of Wisconsin came to the same conclusion in interpreting FIFRA. *Gorton v. American Cyanamid*, 194 Wis. 2d 203 (1995), 533 N.W. 2d 746 (1995).

substantially identical to, requirements imposed by or under the act." *Id.* at 496-97. (Emphasis added).

The plurality concluded that state law actions would be preempted "only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* at 500.

On this issue there was agreement among all Justices. The opinion authored by Justice O'Connor, concurring in part and dissenting in part, joined in by the Chief Justice, Justice Scalia and Justice Thomas, was in full agreement that state tort actions which parallel requirements of the Act are not preempted. Justice O'Connor stated initially that "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would *differ* from those imposed by the FDCA." *Id.* at 509 (emphasis added). Justice O'Connor continued:

> Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is "different from, or in addition to" requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional remedies, but only different or additional requirements.

Id. at 513.

The Justices therefore would unanimously agree that on the narrow issue that when a state misrepresentation action is filed against a manufacturer for making false statements in its marketing materials, and where the Act contains a

similar prohibition against false and misleading statements, then the state law action is not a requirement different from or in addition to the federal requirement. It merely provides a different remedy.

While *Medtronic* did not deal with FIFRA but with the MDA, the language of the preemption clauses is the same. Indeed, the FDA promulgated a regulation stating that the preemption provision in the FDCA "does not preempt state or local requirements that are equal to or substantially identical to requirements imposed by or under the Act." *Medtronic*, 518 U.S. at 496-97, quoting 21 C.F.R. § 808.1(d)(2) (1995).

FIFRA does specifically prohibit false and misleading statements. The regulations for the labeling requirements prohibit:

> (i) a false or misleading statement concerning the composition of the product;
>
> (ii) a false or misleading statement concerning the *effectiveness of the product* as a pesticide or device;
>
> (iii) a false or misleading statement about the value of the product for purposes other than a pesticide or device;
>
> (iv) a false or misleading comparison with other pesticides or devices; . . .
>
> (vii) a true statement used in such a way as to give a false or misleading impression to the purchaser; . . .
>
> (ix) claims as to the safety of the pesticide or its ingredients, including statements such as "safe", "non-poisonous", "non-injurious", "harmless" or "non-toxic to humans and pets" with or without such qualifying phrase as "when used as directed."

See 40 C.F.R. § 156.10 (emphasis added)

The Petitioners in this case raised state law tort claims of strict liability, breach of warranty, fraud, and violations of the Texas Deceptive Trade Practices Act (TDTPA). These allegations make up a partial list of common and oft-repeated allegations one would expect in common-law tort claims against a manufacturer who has made allegedly false claims about its product in its off-label marketing. *See Gorton v. American Cyanamid,* 194 Wis. 2d 203, 533 N.W.2d 746 (1995). ATLA's members have pioneered consumer protection litigation by enforcing state consumer protection laws through filing state civil tort actions based on the foregoing classic allegations.

In this case, Petitioners allege violations of the Texas Deceptive Trade Practices Act, which makes unlawful "representing that goods or services are of a particular standard, quality or grade or that goods are of a particular style or model, if they are of another." Tex. Bus. & Comm. Code § 17.46(b)(7). A violation of the Act occurs when a manufacturer misrepresents the standard or quality of its product in its marketing materials. The Texas Act is not unlike the consumer protection acts that most states have adopted, all of which prohibit falsity in advertising or sales. The same kinds of misrepresentations would also constitute a violation of FIFRA based on the aforementioned regulations 40 C.F.R. § 156.10(a)(5) ii and ix.

Because the tort claim of misrepresentation is a claim parallel to the FIFRA requirement, it is, under both *Cipollone* and *Medtronic*, not "in addition

to or different from" the FIFRA requirement, and thus not subject to preemption. The remedy may differ, but the requirement remains the same.

Starting with the principle that state claims based on allegedly false statements made in a manufacturer's advertisements are not preempted when those claims do not interfere with a federal requirement, and following the reasoning in *Cipollone* and *Medtronic* that state actions parallel or equal to or substantially identical to federal requirements are not preempted, and recognizing that FIFRA requirements prohibit false or misleading statements about the pesticide's effectiveness or safety, one can only conclude that state tort actions for false statements in marketing materials are not preempted under FIFRA.

B. State Court Actions That Give Rise To A Requirement In The Absence Of Any Federal Requirement Are Not Preempted.

There is an additional reason to conclude from *Cipollone* and *Medtronic* that false statements about a pesticide's effectiveness brought in state Court tort actions are not preempted by FIFRA: There cannot be preemption where there is no requirement under the Act.

As discussed above, FIFRA long ago waived efficacy as a labeling requirement, shortly after Congress authorized such a waiver. Since efficacy deals with how a product works when it is used as intended, any false or misleading statements relating to a pesticide's efficacy could not be preempted and would be subject only to remedial actions under state law in the absence of any federal requirement or federal remedy. Congress made clear

in 7 U.S.C. § 136v(a), quoted at n.2, *supra*, that it did not intend that manufacturers escape entirely from accountability under both federal and state law. Rather, Congress underscored that the States retain their historic authority to regulate pesticides and similar products, provided only that they "not permit any sale or use prohibited by this subchapter." *Id.*

Congress intended an orderly federal-state cooperation in regulating pesticides and other potentially harmful products under FIFRA. *See Mortier*, *supra,* at 501 U.S. 601-02. Under the statute's plain language, in the absence of a FIFRA requirement regulating how a product works to aid or protect a crop or a plant, false or misleading statements as to the product's effectiveness or safety fall under state regulation. Preemption of state requirements, in the absence of a federal requirement, would grant unintended immunity to all manufacturer's statements regarding the effectiveness of its products and would leave aggrieved parties without any remedy.

It was not the intent of Congress to create such an immunity for harm to crops when it amended FIFRA to end the regulation of product efficacy by EPA in 1978. Rather, its motivation was similar to that underlying the Medical Device Amendments of 1976: "To the extent that Congress was concerned about protecting the industry, that intent was manifested primarily through fewer substantive requirements under the Act, not the pre-emption provision." *Medtronic, supra,* 518 U.S. at 490. Significantly, the industry favored the waiver of efficacy as a requirement because it lessened the regulatory burden. S. Rep. No. 95-334, at 20 (1977).

Under the similar preemption provision in the Medical Device Amendments, "a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal 'requirement.'" *Medtronic*, 518 U.S. at 496. This Court addressed a similar argument in *Freightliner Corp. v. Myrick,* 514 U.S. 280, 286 (1995). Where Congress did not intend to occupy the field of motor vehicle regulation, but rather preempted any state safety standard "which is not identical to the Federal standard," this Court held that in the absence of a federal standard, "States remain free to 'establish, or to continue in effect,' their own safety standards." *Id.* at 286.

In this case, the waiver of the efficacy requirement left no basis to preempt false claims made by a manufacturer about its product's effectiveness, because the waiver removed it from the regulatory scheme by waiving any federal requirements for efficacy with which a state cause of action could conflict.

Making a false statement about a product's effectiveness which violates state court tort law is not preempted because such statements are both not permitted by and not regulated by FIFRA. Ironically, because falsity in marketing is prohibited by FIFRA but a product's efficacy is not regulated by FIFRA, state consumer protection actions are the sole remedy for damages from ineffective products as well as being the sole enforcement tool available for violation of the federal prohibition against falsity.

Marketing materials are a totally different animal than labels, both in their purpose and content. Marketing materials are not about how to use the pesticide but why the customer should use a specific one. The brochure or publication's purpose is

to convince the end user to buy its product instead of someone else's.

Thus, how to use a pesticide (the label) is as different from why to buy a pesticide (the brochure) as the motivation to protect man and his environment is from the motivation to make a profit on a sale.

We could find no specific authority in FIFRA for the EPA to engage in a review of a manufacturer's marketing claims or selling techniques, nor is it reasonable to assume that Congress would assign such authority to an essentially scientific governmental agency, especially since consumer protection has traditionally been a domain occupied by the states.

The only specific reference we could find appears in the EPA's "Proposed Guidelines for Registering Pesticides in the United States," promulgated in 1980. After an in-depth discussion of why EPA has waived efficacy testing as a requirement for labeling approval, the agency dealt with consumer fraud almost in a passing fashion. In a brief reference, the EPA made clear its view that "consumer fraud is effectively reported and curtailed through existing market institutions, including state regulation processes, USDA and the extension service, farmers associations and the marketplace." 45 Fed. Reg. 72948, 72951 (Nov. 3, 1980). The guidelines also, however, categorically state that the EPA expects that "all registrants will perform the tasks necessary to assure themselves that the products they market will perform their intended functions" and that the EPA "must rely upon the integrity of the industry." *Id.*

Therefore, causes of action against a manufacturer for consumer fraud or deceptive trade practices could not reasonably have been intended to be preempted by Congress. In the absence of EPA regulation to prevent consumer fraud in marketing materials, Congress intended the states to play their role in cooperative regulation of registered products.

III. CROP DAMAGE CLAIMS WOULD NOT BE PREEMPTED UNDER THE MEDTRONIC ANALYSIS

A. The Preemption Clauses Are Markedly Similar

The court below unaccountably ignored this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). This Court there examined the express preemption clause under the MDA, which is remarkably similar to the preemption clause under FIFRA. With Congressional intent being this Court's primary concern, the preemption analysis began with two main principles in the forefront. The first was that there is a long-standing presumption against preemption and that the police powers of the state are not to be superceded by a federal act unless it was the clear and manifest purpose of Congress. 518 U.S. at 485. The second principle was that "the purpose of Congress is the ultimate touchstone" in every preemption case. *Id.* at 486.

The analysis of any preemption clause therefore rests primarily on a fair understanding of Congressional purpose as "discerned from the language of the preemption statute and the statutory framework surrounding it." *Id.* at 485-86. This Court first examined the language of the preemption clause, which reads:

> State and local requirements respecting devices
>
> (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k.

While examining the above language, this Court found the use of the word "requirement" to be significant to its analysis, noting that if Congress intended to preclude all common-law causes of action, "it chose a singularly odd word with which to do it. The statute would have achieved an identical result, for instance, if it had precluded any 'remedy' under state law relating to medical devices." 528 U.S. at 488.

This Court further explained:

> "Requirement" appears to presume that the State is imposing a specific duty upon the manufacturer, and although we have on prior occasions concluded that a statute pre-empting certain state "requirements" could also pre-empt common-law damages claims, [citing *Cipollone*] that statute did not sweep nearly as broadly as Medtronic would have us believe that this statute does."

Id. at 488.

The Court then distinguished the Medical Device Amendments from the statute in *Cipollone*, holding that the territory under the preemptive clause in *Cipollone* was exclusively occupied by federal law as defined in the text of the statute and the word "requirement" is used throughout the entire statute, unlike the MDA, where the word "requirement" is linked "with language suggesting that its focus is device-specific enactments," and "not the application of general rules of common law by judges and juries." *Id.* at 489.

If the *Medtronic* analysis is applied to the preemption clause under FIFRA, it is clear that FIFRA's preemption authority would not extend to crop damage claims.

P.R. Notice 96-4 sets forth the EPA's policy that approval of pesticide labels no longer reflects any determination on the part of the EPA that the pesticide will be efficacious when used as intended or will not cause crop damage. The Congress, by granting the EPA this waiver, clearly did not intend to preserve a product's effectiveness as a domain of FIFRA. On the contrary, it removed efficacy as a requirement and deleted the domain. Thus, when the EPA implemented the waiver, discontinuing efficacy tests as part of the label approval process, congressional intent was satisfied. This effectively removed from the ambit of the preemption clause all such claims for crop damage caused by using a pesticide as intended.

Stated differently, the waiver of efficacy testing as a requirement under the label approval process could be deemed to leave "no requirement" upon which preemption based on efficacy could be

founded. If there are no requirements under FIFRA, state causes of action for crop damages could not be preempted as imposing a requirement in addition to or different from those requirements imposed under the Act.

B. The Facts Are Also Similar

Not only is the preemption clause under FIFRA similar to the preemption clause in *Medtronic*, but the facts in that case are similar to those before this Court. The FDA allowed a pacemaker to be used without the normal rigorous testing to be performed based on the manufacturer's submissions that it was substantially equivalent to another or previous pacemaker. One of the significant holdings in *Medtronic* was that the defective design claims were not preempted because the FDA did not directly test the pacemaker or put it through the normal rigorous testing. Therefore, under *Medtronic*, state actions where the government has not acted are not preempted.

Similarly, the EPA under FIFRA does not test pesticides for safety to crops, delegating instead that control to the marketplace. Under present law, preemption only occurs when it is the clear and manifest purpose of Congress in areas where the EPA acts or regulates. All of the aforementioned are lacking.

The Supreme Court in *Wisconsin Public Intervenor v. Mortier,* 501 U.S. 597 (1999), made clear the limitations of FIFRA. It concluded that Section 136v of FIFRA resulted in a narrow preemptive overlap and Congress did not intend to occupy the entire field of pesticide regulation.

Clearly, the EPA's authority is not exclusive, nor are all state actions prohibited. *Id.* at 606-07.

In *American Cyanamid Co. v. Geye,* 79 S.W. 3d. 21 (Tex. 2002), the Texas Supreme Court dealt with a case where farmers tank-mixed a common combination of pesticides and sprayed targeted areas of crops, which resulted in phytotoxicity, causing damage and plant death. The Court held that Congress has permitted the EPA "to choose not to regulate product labeling with respect to how well a product works, that is, the product's 'efficacy'" and that "the EPA has chosen to define product efficacy to include 'target area phytotoxicity', that is, the effect of a particular product or combination of products on the crops that are deliberately sprayed." *Id.* at 23.

The Court acknowledged that the legislative history showed that the EPA required no crop safety data be submitted in the label approval process, concluding therefrom that crop safety was not an intended domain expressly preempted. *Id.*

Further, the Texas Supreme Court stated that the outcome determinative question before it of whether FIFRA preempted state law damage claims for crop damage did not require an examination of the scope of preemption but rather "the breadth of the congressionally created exception to express preemption." *Id.* The court concluded that "because the scope of FIFRA's preemption is dependent on what the EPA regulates, FIFRA does not preempt the Geyes' common law crop-damage claim." *Id.* at 29.

The *American Cyanamid* opinion accurately assessed the impact of ending efficacy review by EPA

on the scope of FIFRA preemption. Its reasoning, the Fifth Circuit's attempt to distinguish notwithstanding, it fully applicable to this case.

In the present case, discovery has not been conducted, nor has Dow Agrosciences advanced any proofs that EPA had specifically considered the effect upon crops from design, manufacturing methods or claims of safety, all of which formed the basis of the farmers' claims, i.e., strict liability, negligence, negligent misrepresentation and deceptive trade practices. These issues all dealt with the efficacy and safety claims of the herbicide Strongarm and the resulting crop damage from its use. Dow could not have carried its burden because the EPA waived the submission of all data and product testing for those areas with Congress' approval, leaving control of efficacy to the marketplace. Because the EPA does not address these issues during its labeling process, no basis for preemption could be established, and yet the Fifth Circuit mistakenly granted not only preemption but immunity to Dow for all damages caused to users of their product, even when used as intended. It is implausible that Congress would have ever intended this result, especially in light of the fact that it authorized the waiver of testing pesticides for effects upon crops.

Congress enacted FIFRA to protect the public and the environment from harm caused by dangerous substances. The Act attempts to prevent harm before it can happen, while state tort actions compensate victims after harm occurs. State tort actions based on a product's effectiveness were removed from the FIFRA umbrella by Congress, leaving them without federal protection and solely dependent on state law for a remedy.

It is illogical to believe that an Act whose purpose is to protect against harm from pesticides intentionally denies a remedy to those it sought to protect who have been harmed by pesticides.

This Court has the opportunity before it to end a long-term injustice fostered upon and borne by American farmers. That injustice was mistakenly institutionalized by the federal judicial system. Preemption of crop damage claims under FIFRA must end here, and the Court need do nothing more than enforce the intent of Congress clearly demonstrated in its amendments to FIFRA and the EPA's regulations that followed.

CONCLUSION

For the foregoing reasons, ATLA urges this Court to reverse the decision of the Fifth Circuit below.

Respectfully submitted,

R.C. WESTMORELAND
KATHLEEN F. BEERS
WESTMORELAND, VESPER,
SCHWARTZ & QUATTRONE
8025 Black Horse Pike
Suite 500
West Atlantic City, NJ 08232
(609) 645-1111
Attorneys for Amicus Curiae

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